



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0528]

International Conference on Harmonisation; Guidance on E7 Studies in Support of Special Populations; Geriatrics; Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled “E7 Studies in Support of Special Populations: Geriatrics; Questions and Answers.” The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The questions and answers (Q&A) guidance addresses special considerations for the design and conduct of clinical trials of drugs likely to have significant use in the elderly. The Q&As are intended to provide guidance on the use of geriatric data to adequately characterize and represent the safety and efficacy of a drug for a marketing application, including data collected postmarketing.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville,

MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance:

Robert Temple,  
Center for Drug Evaluation and Research,  
Food and Drug Administration,  
10903 New Hampshire Ave.,  
Bldg. 22, rm. 4212,  
Silver Spring, MD 20993-0002  
301-796-2270; or

Nisha Jain,  
Center for Biologics Evaluation and Research (HFM-392),  
Food and Drug Administration,  
1401 Rockville Pike,  
Rockville, MD 20852,  
301-827-6110.

Regarding the ICH:

Michelle Limoli,  
Office of International Programs,  
Food and Drug Administration,  
10903 New Hampshire Ave.,  
Bldg. 32, rm. 3506,  
Silver Spring, MD 20993-0002,  
301-796-4600.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory Agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health,

Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the Federal Register of November 10, 2009 (74 FR 58024), FDA published a notice announcing the availability of a draft guidance entitled “E7 Studies in Support of Special Populations: Geriatrics Questions & Answers.” The notice gave interested persons an opportunity to submit comments by January 11, 2010.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory Agencies in July 2010.

The Q&A guidance addresses special considerations for the design and conduct of clinical trials of drugs that are likely to have significant use in the elderly. The Q&As are intended to provide guidance on the use of geriatric data to adequately characterize and represent the safety and efficacy of a drug for a marketing application, including data collected postmarketing.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on this topic. It does

not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>,  
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,  
or  
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: February 14, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.